Express Mail Label No. EL654377383US 11-24-00 A

# UTILITY PATENT APPLICATION TRANSMITTAL
## (Large Entity)

*(Only for new nonprovisional applications under 37 CFR 1.53(b))*

Docket No. 3553-111US

Total Pages in this Submission 37

11/22/00 jc915 U.S. PTO 09/721107 11/22/00

**TO THE ASSISTANT COMMISSIONER FOR PATENTS**
**Box Patent Application**
**Washington, D.C. 20231**

Transmitted herewith for filing under 35 U.S.C. 111(a) and 37 C.F.R. 1.53(b) is a new utility patent application for an invention entitled:

INTRAVASCULAR STENT

and invented by:

DOMINIK WIKTOR

**If a CONTINUATION APPLICATION,** *check appropriate box and supply the requisite information:*

☒ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: 09/531,097

Which is a:

☒ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: 07/872,737

Which is a:

☒ **Continuation** ☐ **Divisional** ☐ **Continuation-in-part (CIP)** of prior application No.: 07/327,286

**Which is a:**

X **Continuation of prior application No.:** 07/109,686

Enclosed are:

**Application Elements**

1. ☒ Filing fee as calculated and transmitted as described below
2. ☒ Specification having 14 pages and including the following:
   a. ☒ Descriptive Title of the Invention
   b. ☒ Cross References to Related Applications *(if applicable)*
   c. ☐ Statement Regarding Federally-sponsored Research/Development *(if applicable)*
   d. ☐ Reference to Microfiche Appendix *(if applicable)*
   e. ☒ Background of the Invention
   f. ☒ Brief Summary of the Invention
   g. ☒ Brief Description of the Drawings *(if drawings filed)*
   h. ☒ Detailed Description
   i. ☒ Claim(s) as Classified Below
   j. ☒ Abstract of the Disclosure

# UTILITY PATENT APPLICATION TRANSMITTAL
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*(Only for new nonprovisional applications under 37 CFR 1.53(b))*

| Docket No. 3553-111US |
|---|
| Total Pages in this Submission |

**Application Elements (Continued)**

3. ☒ Drawing(s) *(when necessary as prescribed by 35 USC 113)*
   a. ☒ Formal Number of Sheets 6
   b. ☐ Informal Number of Sheets

4. ☒ Oath or Declaration
   a. ☒ Newly executed *(original or copy)* ☐ Unexecuted
   b. ☒ Copy from a prior application (37 CFR 1.63(d)) *(for continuation/divisional application only)*
   c. ☒ With Power of Attorney ☐ Without Power of Attorney
   d. ☐ *DELETION OF INVENTOR(S)*
   Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. 1.63(d)(2) and 1.33(b).

5. ☐ Incorporation By Reference *(usable if Box 4b is checked)*
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4b, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ☐ Computer Program in Microfiche *(Appendix)*

7. ☐ Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all must be included)*
   a. ☐ Paper Copy
   b. ☐ Computer Readable Copy *(identical to computer copy)*
   c. ☐ Statement Verifying Identical Paper and Computer Readable Copy

**Accompanying Application Parts**

8. ☐ Assignment Papers *(cover sheet & document(s))*

9. ☐ 37 CFR 3.73(B) Statement *(when there is an assignee)*

10. ☐ English Translation Document *(if applicable)*

11. ☐ Information Disclosure Statement/PTO-1449 ☐ Copies of IDS Citations

12. ☒ Preliminary Amendment

13. ☒ Acknowledgment postcard

14. ☒ Certificate of Mailing

☐ First Class ☒ Express Mail *(Specify Label No.):* EL654377383US

# UTILITY PATENT APPLICATION TRANSMITTAL
## (Large Entity)

*(Only for new nonprovisional applications under 37 CFR 1.53(b))*

| Docket No. |
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| 3553-111US |
| Total Pages in this Submission |
| 37 |

**Accompanying Application Parts (Continued)**

15. ☐ Certified Copy of Priority Document(s) *(if foreign priority is claimed)*

16. ☒ Additional Enclosures *(please identify below):*

ASSOCIATE POWER OF ATTORNEY

**Fee Calculation and Transmittal**

**CLAIMS AS FILED**

| For | #Filed | #Allowed | #Extra | | Rate | Fee |
|---|---|---|---|---|---|---|
| **Total Claims** | 35 | - 20 = | 15 | x | $18.00 | $270.00 |
| **Indep. Claims** | 5 | - 3 = | 2 | x | $80.00 | $160.00 |
| **Multiple Dependent Claims (check if applicable)** ☐ | | | | | | $0.00 |
| | | | | | **BASIC FEE** | $710.00 |
| **OTHER FEE** *(specify purpose)* _____ | | | | | | $0.00 |
| | | | | | **TOTAL FILING FEE** | $1,140.00 |

☒ A check in the amount of **$1,140.00** to cover the filing fee is enclosed.

☒ The Commissioner is hereby authorized to charge and credit Deposit Account No. **13,2165** as described below. A duplicate copy of this sheet is enclosed.

- ☐ Charge the amount of as filing fee.
- ☒ Credit any overpayment.
- ☒ Charge any additional filing fees required under 37 C.F.R. 1.16 and 1.17.
- ☐ Charge the issue fee set in 37 C.F.R. 1.18 at the mailing of the Notice of Allowance, pursuant to 37 C.F.R. 1.311(b).

*Signature*

Dated: **November 22, 2000**

cc:

3553-111 US

Express Mail Certificate

**Patent Application No. TBA**

Express Mail" Mailing Label Number: EL654377383 US

Express Mail Corporate Account Number: X079384

Date of Deposit: November 22, 2000

Type of Documents:

1. Acknowledgment Post Card;
2 "Express Mail" Certificate
3 Utility Patent Application Transmittal (Large Entity)
4. Our Check Nos.: 24572 for $710.00 and 24588 for $430
5. New Patent Application Entitled: INTRAVASCULAR STENT
6. Specification, Declaration and Power of Attorney Continuing Patent Application
7. Preliminary Amendment
8. Associate Power of Attorney
9. Formal Drawings (6)

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner of Patents, Washington, D.C. 20231; BOX: Patent Application.

Valerie Balfour
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Valerie Balfour
(Signature of person mailing paper or fee)

3553-111US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

| | |
|---|---|
| In re Application of<br>Dominik M. Wiktor<br><br>Serial No. TBA<br><br>Filed: herewith<br><br>For: INTRAVASCULAR STENT | Group Art Unit: TBA<br>Examiner: |

Assistant Commissioner for Patents
Washington, D.C. 20231

SIR:

***PRELIMINARY AMENDMENT***

IN THE SPECIFICATION:

On page 1, lines 3 and 4, rewrite the sentence following the heading "CROSS REFERENCE TO RELATED APPLICATIONS" as follows:

-- This is a continuation of Serial No. 09/531,097 filed March 21, 2000, which in turn is a continuation of Serial No. 07/872,737 filed April 22, 1992, now US Patent No. 6,113,621, which in turn is a continuation of Serial No. 07/327,286 filed March 22, 1989, now US Patent No. 5,133,732 , which in turn is a continuation-in-part of Serial No. 07/109,686 filed October 19, 1987, now US Patent No.4,886,062.--

In the specification:

Please add the following abstract of the invention.

-- A medical device for use in the interior of a body lumen includes a balloon catheter and a radially expandable stent. The stent includes a plurality of zig-zags of a low memory metal formed into a hollow, open-ended cylindrical shape. The individual zig-zags have a curved portion forming a reversing bend which allows the zig-zags to expand and deform as the balloon radially expands the stent. The curved portions of the zig-zags are aligned along the length of the stent in a spaced-apart arrangement with some curved portions attached and others unattached to adjacent zig-zags. The resulting stent is longitudinally flexible throughout its length when unexpanded and is also capable of conforming to a bend in the body lumen when expanded. --

Respectfully submitted,

Bruce M. Collins
Mathews, Collins, Shepherd & Gould, P.A.

Dated: Nov 22, 2000

EXPRESS MAIL NO. NB 189 682 933

# INTRAVASCULAR STENT

## CROSS REFERENCE TO RELATED APPLICATIONS

This is a continuation-in-part of United States Patent Application Serial No. 109,686.

## FIELD OF THE INVENTION

This invention relates to intravascular implants for maintaining vascular patency in humans and animals. The present invention comprises an open-ended wire formed device of basically cylinrical shape and made of a softer-then spring type metal and fitted over an inflatable element of a typical balloon type catheter such as described in U.S. Patent No. 4,195,637 and U.S. Patent No. 4,402,307. The wire formed device is intended to act as a permanent prosthesis stent and is implanted transluminarely. Specifically, this invention is characterized by the ability of said intravascular stent to be enlarged radially after having been introduced percutaneously, transported transluminarely and positioned at desired location. In additiona, this invention relates to a method whereby a permanent prosthesis stent is implanted at the same time the angioplasty procudure is being performed. This invention is particularly useful in transluminar implantation of a stent in the field of cardiology and especially in the case of coronary angioplasty to prevent restenosis.

## BACKGROUND OF THE INVENTION

In my U.S. Patent No. 4,649,992 a device is described in combination with a catheter which is basically a compression spring retained between a partially inflated balloon and an abuttment immediately behind the balloon on the catheter shaft. The intent is to transport the spring prosthesis in this manner to the desired location and then after a successful angioplasty procedure release said spring prosthesis by totally evacuating said balloon, thus

allowing said spring prosthesis to expand linearly and stay in place while the balloon catheter is withdrawn. This method is quite simple and its simplicity is very attractive; however, it has some drawbacks. One and foremost is the fact that the spring has a fixed diameter and as such is unable to fully conform to the inside wall of the vessel which at times is quite tortuous and thus could conceivably create a somewhat turbulant flow of blood, and possible thrombosis could in some cases result. Other patents, e.g. No. 4,553,545 teaches a different method where a relatively complex mechanical rotating device and co-axial cables are employed to achieve the necessary means to change the diameter of the implanted stent to a larger dimension at the point of implant. Still other patents, e.g. No. 3,868,956 describes a method wherein a temperature responsive metallic device is used and expanded after implant using external heat sources. All of the above mentioned devices present drawbacks of various magnitudes including blood coagulation and possible thrombosis and considerable complexity of procedure.

In angioplasty procedures at this time, in many cases restenosis occurs soon thereafter, which requires a secondary procedure or a surgical bypass operation. The implanted prosthesis as described herein will preclude such additional procedures and will maintain vascular patency indefinitely.

Depending on the size used, the stent according to this invention can also be efficacious in other similar applications, such as: repairs of aneurysms, support of artificial vessels or liners of vessels, initial repairs of dissections and mechanical suuport to prevent collapsing of dialated vessels. Still many other and similar applications will be satisfied by this invention without departing from the basic prewise and concept.

This stent and the metod of its use particularly allows a single procedure to combine the essential

angioplasty and a simultaneous implant of a permanent prosthesis designed and intended to prevent restenosis and further complications arising therefrom, also reducing the risk factor and trauma for the patient.

Another use of stents is for aortic dissection.

In the case of aortic dissection, especially a type III dissection of the descending aorta, there is no intravascular stent or prosthesis available, which is both long and flexible enough to repair a typical dissection extending the entire length from the point of origin down to the aortic bifurcation. Also, for the repair of the most difficult and most dangerous dissection, namely the type I which is that of the ascending aorta and the aortic arch, no stent is available today which could be used and be implanted intraluminarely for non-surgical repair of such a dissection. Most intravascular prosthesis and stent available today are of limited length and diameter and are especially limited in terms of flexibility and more specifically in terms of longitudinal flexibility unable to conform to tight bends and adhere to the walls of the intima and at the same time be flexible to stretch and move with each heartbeat such as experienced in the aortic arch.

Therefore, most such cases are treated medically. If surgery is necessary, it often requires the use of hypothermia and cardiopulonary bypass. Surgical procedures of this type involve high risk to the patient, a highly skilled team of cardiovascular surgeons and sophisticated equipment, because it requires the replacement of the affected region with an interpositional graft. High mortality and morbidity are associated with surgery in this region. This is especially true for the elderly and other poor candidates for a major surgery. The cost associated with such a surgical procedure is also very high.

Prior to the development of this invention, there has been no intravascular stent which would satisfy the

following conditions necessary to contemplate a non-surgical repair of a dissecting aorta:

a) To be long enough to extend from the base of the aortic arch down to the aortic bifurcation.

b) To be flexible longitudinally throughout its length.

c) To be radially expandable easily, a small section at a time using common dilatation balloon or similar expanding device designed for that purpose.

d) To be radially expandable to various diameters and to conform to tortuous conditions of a diseased aorta.

e) To be non-obstructive to all branches.

f) To be clearly visible on Floroscope both during deployment and post-operatively to visibly ascertain its condition, location and efficacy.

g) To be implantable permanently, retrograde and be able to completely obliterate a false lumen of a dissection and to maintain patency of the main lumen as well, as the patency of all side branches throughout its length.

Other reference publications:

1. Self-Expanding Metalic Stents for Small Vessels Radiology 1987 - 162.469-472.
2. Flexible Balloon-Expandable Stent for Small vessels, Radiology, Jan. 1987.
3. Intravascular Stents to Prevent Occlusion and Restenosis After Transluminar Angioplasty, N.E.J. of M., March 19, 1987.
4. U.S. Patent No. 4,580,568, Percutaneous Endovascular Stent.
5. U.S. Patent No, 4,503,569, Transluminarely Placed Expandable Graft Prosthesis, Dotter 1985.
6. U.S. Patent No. 4,649,992, Catheter Arrangement Having a Variable Diameter Tip and Spring Prosthesis, Wiktor 1987.

7. U.S. Patent No, 4,681,110, Catheter Arrangement and Blood Vessel Liner, Wiktor 1987.

All of the above references describe and teach various methods of providing or otherwise offering and introducing stents of different types and designs for applications similar to the one described herein in this invention.

## SUMMARY OF THE INVENTION

The improvement of this invention over other similar devices such as cited in patents above, and specifically my previus invention described in U.S. Patent No. 4,649,992, is the ability of the device of this invention to allow for and to maintain a very low profile and a small frontal area, so very important for purposes of percutaneous insertion. Thus the stent of this invention can be inserted into and be transported via a standard #8F Guiding Catheter such as USCI Cat. #006128, while using standard procedures and methods. Once on location, the stent can be expanded radially to a diameter larger than initially introduced; a ratio of = 2 1/2 : 1 can easily be achieved with a wire diameter of .008 and initial stent diameter of .075. The expanded larger diameter will conform to the inside of the vessel and maintain intimate contact with the inside wall. The stent of this invention is characterized by the low memory level of the relatively easily deformable metal used for the wire.

The configuration of stent 1, shown in Fig. 1, is such that the wire 2 is intially preformed into a two-dimensional zig-zag form 3, basically creating a flat expandable band 3a. The zig-zag pattern can vary as to its shape and tightness of the reversing bends, but for reasons of simple description a typical sinusoidal form is chosen to depict this band's construction.

In order to create the stent 1, and to have it assume an initial configuration as shown in Fig. 1, also a subsequently radially expanded condition as shown in Fig.

5, a length of preformed band 3a is wrapped on a suitable mandrel 4 in a manner similar to that of winding a simple helical spring again as shown in Fig. 1. Care is taken to form the wire band 3a flat around the mandrel 4 with little or no tension to prevent premature linear expansion of band 3a.

Once the zig-zag band 3a is wound into a cylindrical shape, it is removed from the mandrel 4, and is placed over a suitable variable diameter device such as an inflatable balloon 5 typically used for angioplasty procedures as shown in Fig. 2. A suitable forming tool (not shown) is used to tighten the stent over the balloon; manual operation of squeezing the stent over the balloon is also acceptable.

A controlled radial expansion of the stent is accomplished by the force generated by the inflating balloon. When acted upon by the inflating balloon, the stent of this invention being characterized by the zig-zag preformed wire band 3a subsequently formed into an open-ended cylindrical shape, is by design and intent capable to expand radially.

The radial expansion in effect is achieved by controlled deformation and tension applied to the sinusoidal pattern of the preformed wire band 3a. The low memory metal used for the fabrication of the wire formed stent assures, that the radially expanded stent stays expanded thus fulfilling is preimary intent and function. Other advantages of this invention over those mentioned earlier Ref. 1 through 7, are the inherent post-expansion radial rigidity and linear flexibility, an excellent combination for an intravascular and especially intracoronary stent. In the case of intracoronary application, an overriding factor being the ability of allow for an extremely low profile and a very small frontal area so very essential for initial transluminar introduction and transportation through a standared 8F guiding catheter.

A major object of this invention is the provision of a preformed flexible wire stent which allows easy radial expansion and subsequent retention of the radially expanded shape well anchored within a vessel. Still anther object of this invention is the simplicity of its application, especially with respect to angioplasty, where one procedure accomplishes two distinct functions: In combination with the balloon it compresses the plaque, thus creating a recannalized lumen as characterized by angioplasty, and deploys and implants a permanent prosthesis within the newly created and recannalized lumen to prevent possible reclosure and restenosis thus allowing free flow of blood indefinitely. Both functions are performed simultaneously and with a single insertion of the catheter.

There is a need for a means to restrain an extra long stent from excessive stretching. This invention includes means for preventing a longitudinal overstretch of the stent, particularly during the initial introduction into the vessel where several constrictions occur. The introduction of the stretch limiting means guarantees a constant and uniform pitch of the helical wire formed coil throughout the entire length of the stent both in its non-expanded and especially in its expanded condition and still maintains full flexibility. The longitudinal stretch limiting means can take several forms including a straight wire placed on the outside of the tubular shaped stent spotwelded to each individual coil or alternately using a simple suture thread and tying each coil to the next. Another method found acceptable is to arrange the sinusoidal wave shape pattern where one wave shape out of a series is longer and can be bent to catch the wave of the adjacent coil.

The invention includes means for restraining coils of the helix from longitudinal movement relative to each other. In other words, means are provided for restraining lengthwise stretch of the coil. To one embodiment, the

means includes a single lengthwise wire attached, for example, by welding to loops of the coil. In another embodiment, the loop of the coil is hooked over an adjacent loop to restrain longitudinal movement.

## BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a side elevation of a preferred embodiment of a stent according to this invention being wound on a mandrel;

Fig. 2 is a side elevation showing an overall view of a stent prosthesis fitted over a deflated balloon;

Fig. 3 shows the balloon and stent assembly advanced within a vessel, approaching a partial occlusion;

Fig. 4 is similar to Fig. 3 showing the balloon and stent assembly inside a partially occluded vessel;

Fig. 5 is similar to Fig. 4, the balloon inflated, and the stent radially expanded, illustrating the preferred method of an angioplasty procedure coupled with a simultaneous deployment and implantation of a permanent prosthesis stent; and

Fig. 6 is a view similar to Fig. 5 showing the prosthesis stent implanted and plaque compressed and retained after removal of the balloon.

Fig. 7 shows the stent with one type of a longitudinal over-stretch limiting means.

Fig. 8 shows the stent yet with another means to prevent longitudinal over-stretch.

Fig. 9 shows a cross-sectional view of a typical dissection of the descending aorta including a false lumen and the expanding device and stent assembly advanced into position for first expansion.

Fig. 10 shows the same cross-section of the aorta as in Fig. 9 with the flexible balloon pressurized with radio-opaque fluid and expanded.

Fig. 11 shows the aorta of Fig. 10, showing the first part of the stent fully expanded, origin of dissection

obliterated and expanding device repositioned for next sequential expansion.

Fig. 12 depicts the next sequential expansion of the stent after Fig. 11.

Fig. 13 shows the stent fully expanded and implanted, false lumen obliterated and type III aortic dissection repaired, and expanding device withdrawn, procedure completed.

## DESCRIPTION OF THE PREFERRED EMBODIMENT

For purposes of better and clearer understanding of this invention, reference is made to Figs. 1-6. The preferred embodiment of this invention is shown and described in an application for angioplasty; however, it is understood that other applications not specifically mentioned herein are ossible and no limitations in scope of this invention are intended or implied without departing from the basic principles of this invention.

Fig. 1 shows the details of construction of the prosthesis stent 1, hereafter called stent, which is basically of a hollow open-ended cylindrical shape. Stent 1 is basically a tubular shape of coiled preformed wire band typically wound on a suitable mandrel 4. The wire is made of drawn low-memory level material such as stainless steel, titanium ASTM F63-83 Grade 1 or high carat gold K 19-22. Copper alloy typically 110 when properly coated with polyester or Teflon® can also be used. Titanium and gold are biologically compatible and inert and requires no special treatment.

In Fig. 2, it is shown that the stent 1 is centrally located and positioned with respect to the length of balloon 5 and that flat preformed wire band 3a turns are evenly spaced so that when stent 1 is expanded as shown in Fig. 5 and Fig. 6, stent 1 will provide even support inside vessel 8, and be able to resist external loading.

In Fig. 3, it is shown how balloon and stent assembly 5a emenate from guiding catheter 9 inside vessel 8 and is advanced towards partial occlusion 10.

In Fig. 4, it is shown how balloon and stent assembly 5a are located inside occlusion 10 within arter 8, balloon 5 still being deflated. Once positively placed within occlusion 10, balloon 5 is inflated using standard angioplasty procedures and techniques. As balloon 5 expands, so does the stent 1 as shown in Fig. 5. The expanding balloon 5 together with stent 1 compresses the plaque 7, said plaque remains compressed and stent 1 retains said plaque 7 and prevents possible reocclusion. Angioplasty procedure complted, balloon 5 is deflated and withdrawn leaving stent 1 firmly implanted within vessel 8. Previously occluded vessel 8 is now completely recannalized and patency is restored.

Fig. 6 shows stent 1 firmly implanted and imbedded in compressed plaque 7, providing both adequate support as well as a smooth lumen void of all protrusions, a very desirable feature and condition, since any protrusions are conductive to turbulant blood flow and potential formation of thrombosis.

To test the viability of this novel principle of stent construction, a polyester-coated copper wire of .008 diameter was preformed into a zig-zag pattern 3 as shown in Fig. 1 to form a band 3a. This band was subsequently wound into a tubular shape with ends curled into tight loops 2a to prevent sharp ends of wire 2 from perforating balloon 5. The tubular stent was placed over a 3.5mm PTCA 20/3.5T balloon made by SciMed and fitted tightly over said balloon. The balloon and stent assembly was fed through an 8F guiding catheter into a silastic thin-wall tubing approximately 3mm inside diameter and balloon was inflated with a standard 10 cc syringe using plain water. The expansion of the stent was observed and documented on video. Several subsequent tests of similar nature also using larger balloons typically MeadoxSurgimed A/S Cat.

No. 700720 10mm dia. and Medi. tech balloon 12mm dia. were used with a stent made of polyester-coated copper wire .014" dia. All tests showed near perfect expansion and "bench-type" implantations. Further experiments showed that multiple stents can be used in tandem. In fact, a typical balloon and stent assembly can be fed right through a previously implanted and expanded stent and be implanted downstream ahead of the previously implanted stent. A distinct advantage in real life situations.

Experimental laboratory tests on animals are now being conducted. Initial results are very encouraging and promising. Both intracoronary and intraaortic stents are being investigated at this time, a complete protocol is being prepared.

Five stents recently implanted in small arteries of pigs and expanded to 3.5mm have successfully maintained 100% patency for several weeks and as of this date continue to do so.

In sparate experiment, a previously aortic dissection has been stopped by expanding a 10mm diameter stent within said dissection.

The embodiment of the present invention involving means for preventing longitudinal overstretching is illustrated in Fig. 7. Stent 20 has a generally cylindrical body 22 formed by winding wire 24 in the cylindrical shape, as discussed above. Wire 24 has an end 26 which has a loop 28 hooked over wire 24.

Wire 24 has been formed with zig-zags or waves 30, as in the embodiments discussed above. A longitudinal wire 32 is attached, preferably by welding, to waves 30 of wire 24 at points 34.

Wire 32 prevents stent 20 from expanding along the longitudinal axis of wire 32. Radial expansion of the cylindrical body 22 is accomplished by stretching waves 24, as in the embodiments discussed above.

The structure of Fig. 7 is particularly suitable for long stents which may be more susceptible to stretching. One example is in the case of aortic dissections.

In Fig. 8, it is illustrated an alternative embodiment of means for preventing longitudinal overstretch in a stent constructed according to the present invention. Stent 40 has a generally cylindrical body 42 formed of wire 44. Wire 44 has zig-zags or waves 46.

Certain of waves 46 are longer than others, such as waves 48. In this embodiment, one out of four of waves 46 is elongated as is wave 48.

Elongated waves 48 are bent to form a loop or hook 50. Each hook 50 is looped over a wave 46 adjacent. The engagement of hooks 50 with previous waves 48 prevents longitudinal spread of the cylindrical body 42 of stent 40.

In Fig. 9, a typical type III aortic dissection is illustrated where the aorta 50 is depicted in a cross-sectional view, and the flow of blood is shown by arrows 52. Blood partially enters the origin of dissection 54, creating a false lumen 56 by delaminating the aortic wall 58. The expanding device such as balloon 60 and stent assembly 62 is shown in a side elevation view inside the aorta 50. Balloon 60 is advanced to the point of origin of dissection 54. Balloon 60 transports extra long stent 62 and positions it within the aorta 50 for initial steps of repair. In Fig. 10, balloon 7 is shown filled with radiopaque liquid. Balloon 60 expands the stent 63 into a nearly straight wire coil 64, forcing the false lumen 56 to regress and at this point to re-laminate the aortic wall 58.

Fig. 11 illustrates the expanding device 60 and stent 62 after the first stage of stent implant successfully completed, in a deflated and deactivated mode being repositioned for the next sequential procedure to expand the next portion of stent and to obliterate the next

section of said false lumen 56. Fig. 12 illustrates the next portion of said false lumen 56 being obliterated by the expanding stent similar to that shown in Fig. 12.

Finally, Fig. 13 illustrates the entire length of the aorta 50 having been fitted and lined with a long flexible stent 62, said stent 62 being firmly implanted the false lumen completely obliterated and aortic dissection type III fully repaired.

For situations where a long stent may be subjected to longitudinal stretching, either during insertion or during physiologic movement, stents constructed according to the present invention improve upon the prior art by including means for preventing longitudinal stretch. While this improvement has been disclosed in terms of particular embodiment, the prevention of longitudinal stretch by coil-type stents is a desirable goal and is facilitated by this invention.

II. CLAIMS

1. A stent for implantation within a body vessel comprising:

a cylindrical stent body formed of generally continuous wire, the stent body having a first diameter and a first length along the longitudinal axis; and

means for preventing longitudinal stretch of the body.

2. The stent of claim 1 wherein body is a coil of successive windings and the means for preventing longitudinal stretch includes a wire positioned along the cylindrical stent body and attached to successive windings of the wire at its crossing points.

3. The stent of claim 1 wherein:

the body is constructed of a helical coil of wire and further comprising:

zig-zag means in the wire generally in the form of a sinusoidal wave wherein selected individual waves are hooked over waves of an adjacent winding of the helical coil.

4. A stent for implantation within a body vessel comprising:

a cylindrical stent body formed of a continuous wire formed in a generally helical coil made of successive windings, the cylindrical body having a longitudinal axis; and

means for connecting adjacent windings of a cylindrical body for preventing stretching of the helical coil along the longitudinal axis.

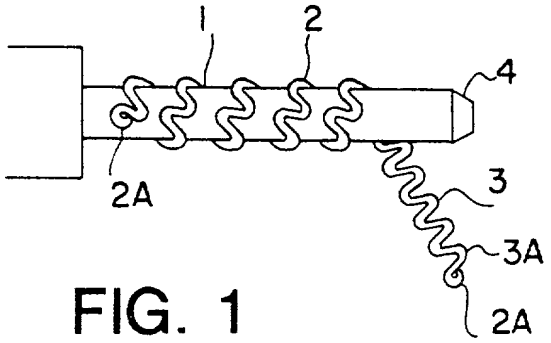


FIG. 1

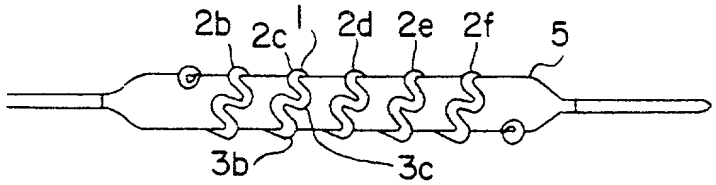


FIG. 2

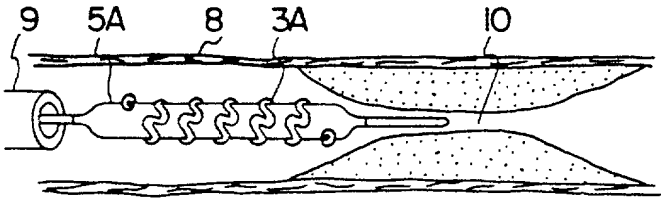


FIG. 3

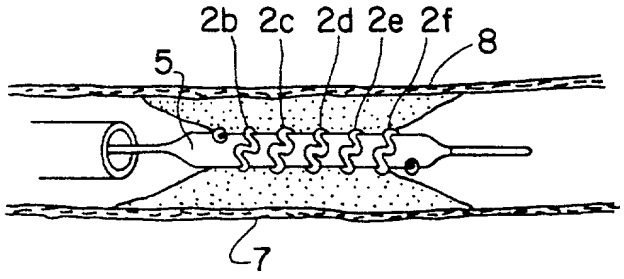


FIG. 4

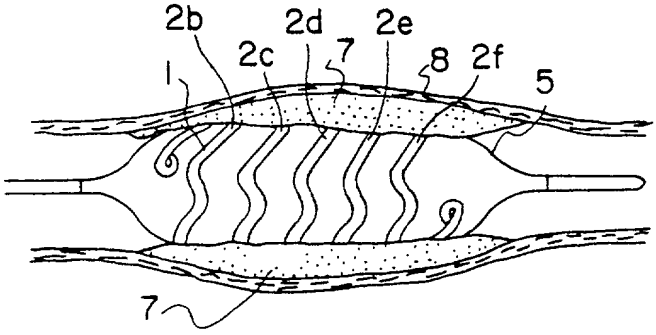


FIG. 5

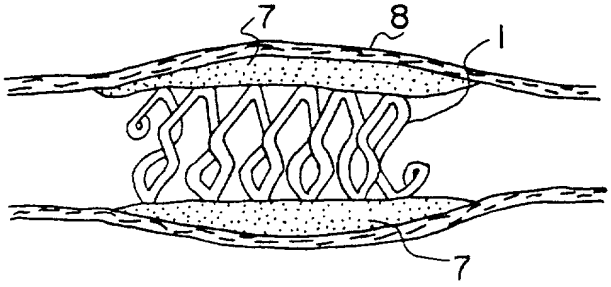


FIG. 6

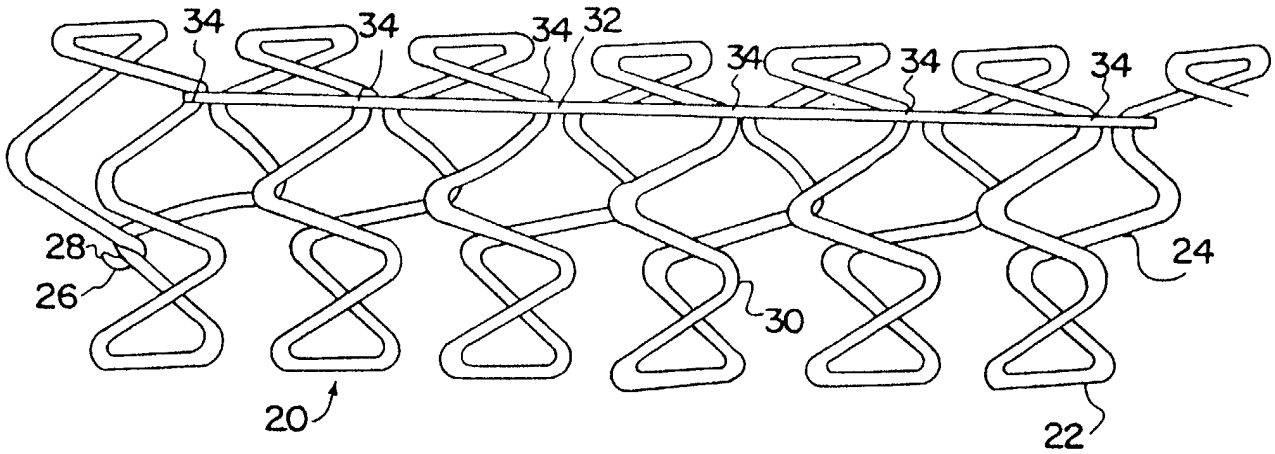


FIG. 7

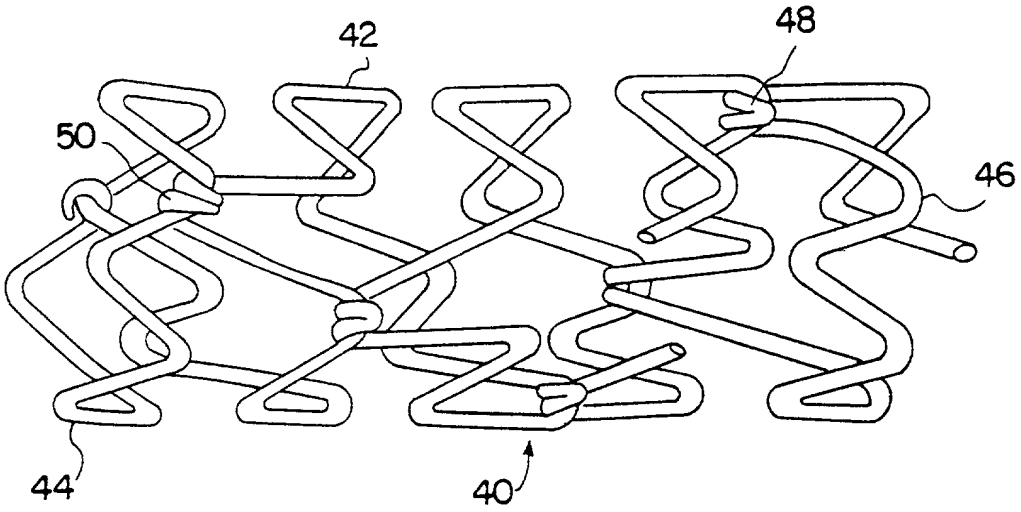


FIG. 8

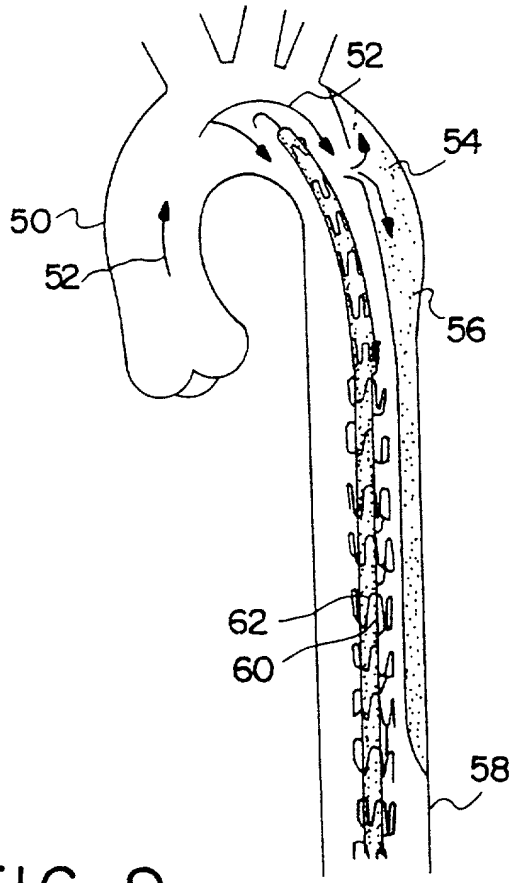


FIG. 9

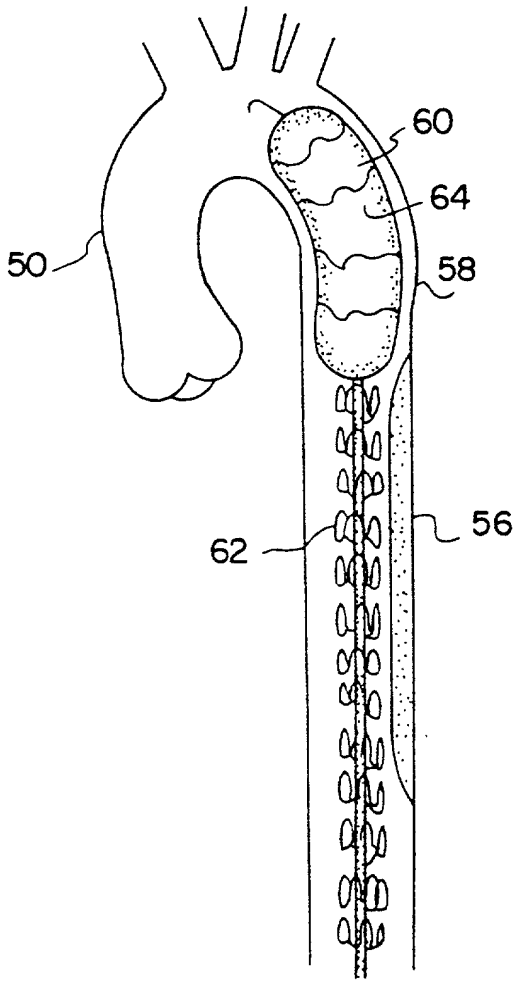


FIG. 10

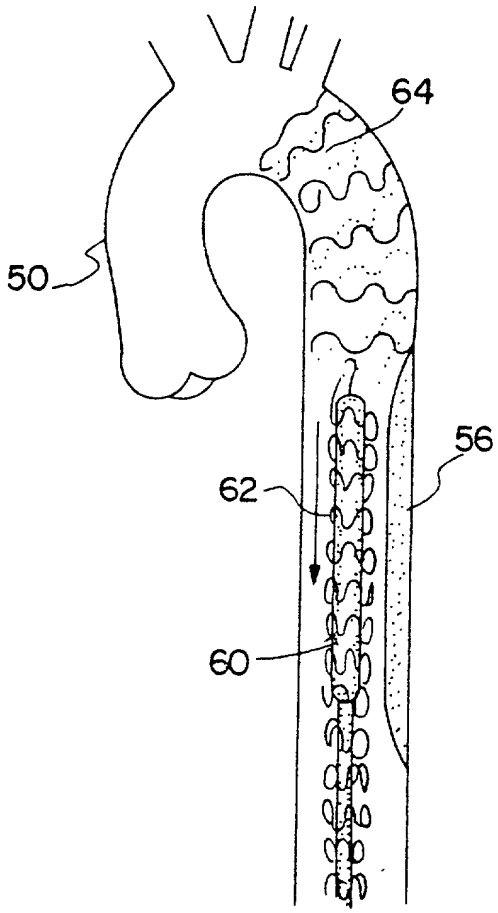


FIG. 11

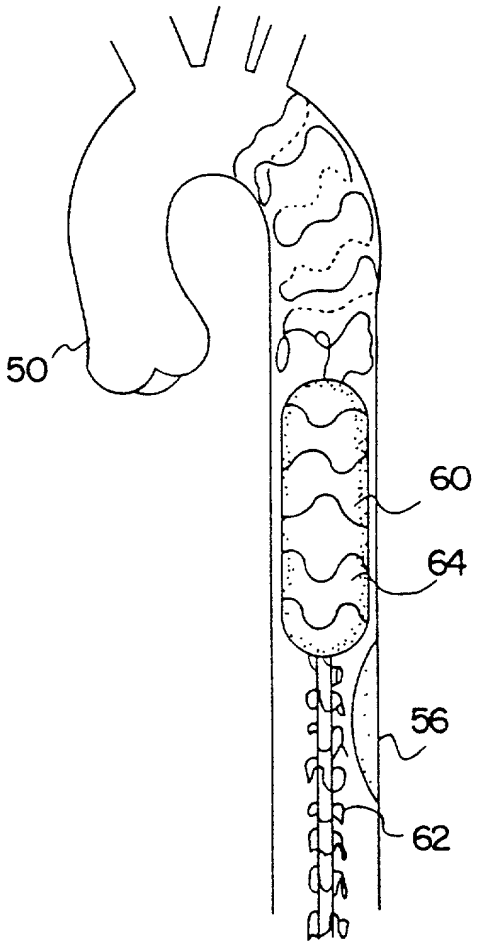


FIG. 12

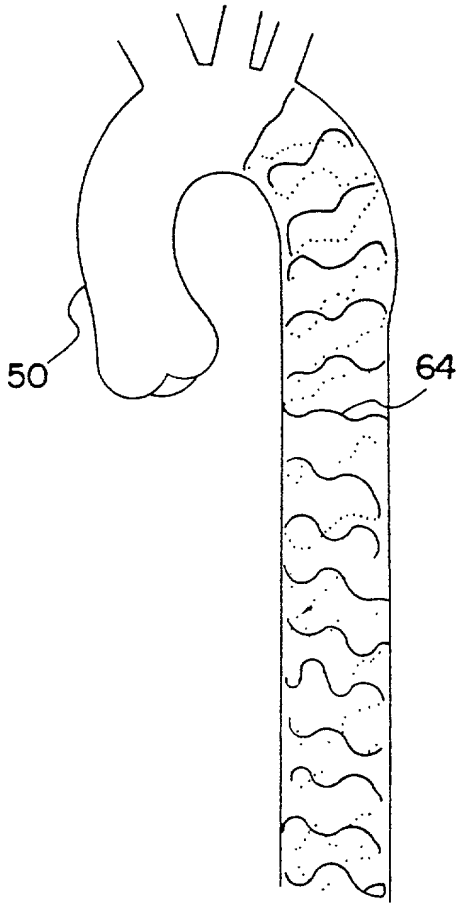


FIG. 13

**Practitioner's Docket No.** P-804 C6 ***PATENT***

## COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

### TYPE OF DECLARATION

This declaration is of the following type:

*(check one applicable item below)*

☐ original.

☐ design.

*NOTE: With the exception of a supplemental oath or declaration submitted in a reissue, a supplemental oath or declaration is not treated as an amendment under 37 CFR 1.312 (Amendments after allowance). M.P.E.P. § 714.16, 7th Edition.*

☒ supplemental.

*NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application, do not check next item; check appropriate one of last three items.*

☐ national stage of PCT.

*NOTE: If one of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR C-I-P.*

*NOTE: See 37 C.F.R. § 1.63(d) (continued prosecution application) for use of a prior nonprovisional application declaration in the continuation or divisional application being filed on behalf of the same or fewer of the inventors named in the prior application.*

☐ divisional.

☐ continuation.

*NOTE: Where an application discloses and claims subject matter not disclosed in the prior application, or a continuation or divisional application names an inventor not named in the prior application, a continuation-in-part application must be filed under 37 C.F.R. § 1.53(b) (application filing requirements — nonprovisional application).*

☐ continuation-in-part (C-I-P).

### INVENTORSHIP IDENTIFICATION

***WARNING:*** *If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.*

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor *(if only one name is listed below)* or an original, first and joint inventor *(if plural names are listed below)* of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

### TITLE OF INVENTION

INTRAVASCULAR STENT

## SPECIFICATION IDENTIFICATION

the specification of which:

*(complete (a), (b), or (c))*

(a) XXX is attached hereto.

*NOTE: "The following combinations of information supplied in an oath or declaration filed on the application filing date with a specification are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 CFR 1.63:*

*"(1) name of inventor(s), and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration on filing;*

*"(2) name of inventor(s), and attorney docket number which was on the specification as filed; or*

*"(3) name of inventor(s), and title which was on the specification as filed."*

*Notice of July 13, 1995 (1177 O.G. 60).*

(b) ☐ was filed on _____, as ☐ Serial No. 0 /_____ or ☐ _____ and was amended on _____ *(if applicable).*

*NOTE: Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 C.F.R. § 1.67.*

*NOTE: "The following combinations of information supplied in an oath or declaration filed after the filing date are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 CFR 1.63:*

*"(A) application number (consisting of the series code and the serial number, e.g., 08/123,456);*

*"(B) serial number and filing date;*

*"(C) attorney docket number which was on the specification as filed;*

*"(D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or*

*"(E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration."*

*M.P.E.P. § 601.01(a), 7th Ed.*

(c) ☐ was described and claimed in PCT International Application No. _____, filed on _____ and as amended under PCT Article 19 on _____ *(if any).*

## SUPPLEMENTAL DECLARATION (37 C.F.R. § 1.67(b))

*(complete the following where a supplemental declaration is being submitted)*

☒ I hereby declare that the subject matter of the

☒ attached amendment

☐ amendment filed on _____

was part of my/our invention and was invented before the filing date of the original application, above-identified, for such invention.

## ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56,

*(also check the following items, if desired)*

☐ and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and

☐ in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 C.F.R. § 1.98.

## PRIORITY CLAIM (35 U.S.C. §§ 119(a)–(d))

NOTE: *"The claim to priority need be in no special form and may be made by the attorney or agent if the foreign application is referred to in the oath or declaration as required by § 1.63. The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) must be filed in the case of an interference (§ 1.630), when necessary to overcome the date of a reference relied upon by the examiner, when specifically required by the examiner, and in all other situations, before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by a petition requesting entry and by the fee set forth in § 1.17(i). If the certified copy is not in the English language, a translation need not be filed except in the case of interference; or when necessary to overcome the date of a reference relied upon by the examiner; or when specifically required by the examiner, in which event an English language translation must be filed together with a statement that the translation of the certified copy is accurate." 37 C.F.R. § 1.55(a).*

I hereby claim foreign priority benefits under Title 35, United States Code, §§ 119(a)–(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

*(complete (d) or (e))*

(d) ☒ no such applications have been filed.

(e) ☐ such applications have been filed as follows.

NOTE: *Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.*

## PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)

| COUNTRY (OR INDICATE IF PCT) | APPLICATION NUMBER | DATE OF FILING (day, month, year) | PRIORITY CLAIMED UNDER 37 USC 119 |
|---|---|---|---|
| | | | ☐ YES NO ☐ |
| | | | ☐ YES NO ☐ |
| | | | ☐ YES NO ☐ |
| | | | ☐ YES NO ☐ |
| | | | ☐ YES NO ☐ |

## CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)

(34 U.S.C. § 119(e))

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

| PROVISIONAL APPLICATION NUMBER | FILING DATE |
|---|---|
| _____ /_____ | _____ |
| _____ /_____ | _____ |
| _____ /_____ | _____ |

## CLAIM FOR BENEFIT OF EARLIER US/PCT APPLICATION(S) UNDER 35 U.S.C. § 120

☒ The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN PART (C-I-P) APPLICATION.

**ALL FOREIGN APPLICATION(S), *IF ANY*, FILED MORE THAN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

_____

_____

_____

*NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.*

## POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

*(list name and registration number)*

Harold R. Patton, Reg.No.22,157; Reed A. Duthler, Reg.No.30,626; Daniel W. Latham, Reg.No.30,401; Michael J. Jaro, Reg.No.34,472; Curtis D. Kinghorn, Reg.No.33,926; Thomas F. Woods, Reg.No.36,726; Girma Wolde-Michael, Reg.No.30,724; Eric R. Waldkoetter, Reg.No.36,713

*(check the following item, if applicable)*

☐ I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

☐ Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

*NOTE: "Special care should be taken in continuation or divisional applications to ensure that any change of correspondence address in a prior application is reflected in the continuation or divisional application. For example, where a copy of the oath or declaration from the prior application is submitted for a continuation or divisional application filed under 37 CFR 1.53(b) and the copy of the oath or declaration from the prior application designates an old correspondence address, the Office may not recognize, in the continuation or divisional application, the change of correspondence address made during the prosecution of the prior application. Applicant is required to identify the change of correspondence address in the continuation or divisional application to ensure that communications from the Office are mailed to the current correspondence address. 37 CFR 1.63(d)(4)." § 601.03, M.P.E.P., 7th Edition.*

SEND CORRESPONDENCE TO

Daniel W. Latham

☒ Address

Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, Minnesota 55432

☐ Customer Number _____

DIRECT TELEPHONE CALLS TO:
*(Name and telephone number)*

(763) 514-3278

*(complete the following if applicable)*

Since this filing is a ☐ continuation ☐ divisional there is attached hereto a Change of Correspondence Address so that there will be no question as to where the PTO should direct all correspondence.

## DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

## SIGNATURE(S)

*NOTE: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents.*

*NOTE: Each inventor must be identified by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and by his/her residence, post office address and country of citizenship. 37 CFR § 1.63(a)(3).*

*NOTE: Inventors may execute separate declarations/oaths provided each declaration/oath sets forth all the inventors. Section 1.63(a)(3) requires that a declaration/oath, inter alia, identify each inventor and prohibits the execution of separate declarations/oaths which each sets forth only the name of the executing inventor. 62 Fed. Reg. 53,131, 53,142, October 10, 1997,*

**Full name of sole or first inventor**

Dominik (*GIVEN NAME*) M. (*MIDDLE INITIAL OR NAME*) Wiktor (*FAMILY (OR LAST NAME)*)

**Inventor's signature** Dominik M Wiktor

**Date** 03-13-2000 **Country of Citizenship** US

**Residence** St. Petersburg Beach, Florida US

**Post Office Address** 6441 - 3rd Palm Point, St. Petersburg Beach, Florida 33706

---

**Full name of second joint inventor, if any**

(*GIVEN NAME*) (*MIDDLE INITIAL OR NAME*) (*FAMILY (OR LAST NAME)*)

**Inventor's signature** _____

**Date** _____ **Country of Citizenship** _____

**Residence** _____

**Post Office Address** _____

---

**Full name of third joint inventor, if any**

(*GIVEN NAME*) (*MIDDLE INITIAL OR NAME*) (*FAMILY (OR LAST NAME)*)

**Inventor's signature** _____

**Date** _____ **Country of Citizenship** _____

**Residence** _____

**Post Office Address** _____

*(check proper box(es) for any of the following added page(s) that form a part of this declaration)*

☐ **Signature** for fourth and subsequent joint inventors. *Number of pages added* _____.

* * *

☐ **Signature** by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. *Number of pages added* _____.

* * *

☐ **Signature** for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47. *Number of pages added* _____

* * *

☐ Added page for **signature** by one joint inventor on behalf of deceased inventor(s) where legal representative cannot be appointed in time. (37 CFR 1.47)

* * *

XX Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application.

☐ Number of pages added _____

* * *

☐ Authorization of practitioner(s) to accept and follow instructions from representative.

* * *

*(if no further pages form a part of this Declaration, then end this Declaration with this page and check the following item)*

☐ This declaration ends with this page.

**Practitioner's Docket No.** P-804 C6

## ADDED PAGE TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION

*(complete this part only if this is a divisional, continuation or C-I-P application)*

### CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. 120

I hereby claim the benefit, under Title 35, United States Code, § 120, of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information

☒ that is material to patentability as defined in 37, Code of Federal Regulations, § 1.56

*(also check the following item, if desired)*

☐ and that is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent,

that occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application. (37 C.F.R. § 1.63(e)).

*(also check the following item, if desired)*

☐ In compliance with this duty, there is attached an information disclosure statement, in accordance with 37 C.F.R. 1.98.

| PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 USC 120: | | | | |
|---|---|---|---|---|
| U.S. APPLICATIONS | | Status (*check one*) | | |
| U.S. APPLICATIONS | U.S. FILING DATE | Patented | Pending | Abandoned |
| 1.0 / 109,686 | October 19, 1987 | X | | |
| 2.0 / 327,286 | March 22, 1989 | X | | |
| 3.0 / 872,737 | April 22, 1992 | | X | |

| PCT APPLICATIONS DESIGNATING THE U.S. | | |
|---|---|---|
| PCT APPLICATION NO. | PCT FILING DATE | U.S. APPLICATION NOS. ASSIGNED (*if any*) |
| 4. | | 0 / |
| 5. | | 0 / |
| 6. | | 0 / |

## 35 USC 119 PRIORITY CLAIM, IF ANY, FOR ABOVE LISTED U.S./PCT APPLICATIONS

| ABOVE APPLICATION NO. | DETAILS OF FOREIGN APPLICATION FROM WHICH PRIORITY CLAIMED UNDER 35 USC 119 | | |
|---|---|---|---|
| | **Co untry and Application No.** | **Date of filing (day, month, year)** | **Date of issue (day, month, year)** |
| 1. | | | |
| 2. | | | |
| 3. | | | |
| 4. | | | |
| 5. | | | |
| 6. | | | |

3553-MUS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of
Dominik M. Wiktor,

Serial No. 09/531,097

Filed: March 21, 2000

For: INTRAVASCULAR STENT

Group Art Unit: 3731
Examiner:

Assistant Commissioner for Patents
Washington, D. C. 20231

SIR:

***ASSOCIATE POWER OF ATTORNEY***

Please recognize Bruce M. Collins, Reg. No. 20,086, Ronald Gould, Reg. No. 28,299, Diane Dunn McKay, Reg. No. 34,586, Glen E. Books, Reg. No. 24,950, Timothy X. Gibson, Reg. No. 40,618, David P. Krovoshik, Reg. No. 39,258 and Mary S. Kakefuda, Reg. 39,245 all of the firm of Mathews, Collins, Shepherd & Gould, P.A., 100 Thanet Circle, Suite 306, Princeton, New Jersey 08540 as associate attorneys of record in the above application, with full powers to take any and all action therein in the U.S. Patent and Trademark Office.

All written communication should be directed to:

Daniel W. Latham
Medtronic, Inc.
7000 Central Avenue NE
Minneapolis, MN 55432

Telephone calls and telecopier transmissions should be directed to Daniel W. Latham at the following telecommunication numbers: Telephone, (612)514-3278; Facsimile, (612)514-3233.

Respectfully submitted,

Daniel W. Latham
Reg. No. 30,401
Attorney for Applicants